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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/733,617 | 12/11/2003 | Ming-qun Xu | NEB-214-US | 9524 |

28986 7590 08/28/2006

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| EXAMINER |
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VENCI, DAVID J

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/733,617 | XU ET AL. | |
| | Examiner | Art Unit | |
| | David J. Venci | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 8, 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action is withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on June 8, 2006, is entered.

Currently, claims 1-8 are under examination.

Claims 9-31 are drawn to non-elected inventions and remain withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the terms "intein" and "carrier-intein fusion protein" are indefinite. According to Applicants' specification, an "intein" is a "self-splicing protein" (see Specification, p. 20, lines 5-8). However, Examiner is unable to correspond a "self-splicing protein" to any object in claim 1. Clarification is required.

In claims 4, 5 and 7, the phrase "the matrix-binding molecule" lacks antecedent basis.

Claim Rejections - 35 USC § 102

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Muir *et al.* (US 6,875,594).

Muir *et al.* describe a method for purifying a ligand-binding molecule from a mixture, comprising:

(a)(b) forming a carrier-ligand conjugate by reacting a C-terminal thioester (see Fig. 2A, product of step 2) on a carrier/ligand (see Fig. 2A, "Recomb. Protein"), with a nucleophilic group (see Fig. 2A, "thiophenol") (emphasis added) on a ligand/carrier (see Fig. 2A, "thiophenol") (emphasis added), wherein cleaving a carrier-intein fusion protein or a ligand-intein fusion protein generates the C-terminal thioester (see *e.g.*, col. 10, lines 40-41, "fragmenting the recombinant protein"; col. 14, lines 49-51, "thiophenol was found to be the only co-factor tested that supported both efficient cleavage and efficient ligation"; Fig. 2A, step 3); and binding the carrier-ligand conjugate to a matrix (see *e.g.*, col. 10, lines 46-47, "ligating by the method provided herein"; col. 19, lines 64+, "[t]he 'protein' component of a protein chip as used herein is the ligation product of an oligopeptide and a recombinantly expressed protein..."; Fig. 2A, step 4);

(b) contacting the carrier-ligand conjugate with a mixture containing the ligand-binding molecule to selectively bind the ligand-binding molecule to the carrier-ligand conjugate (see col. 33, lines 9-10, "sample from a subject is incubated with the protein chip"; line 12, "protein-protein binding"); and

(c) eluting the ligand-binding molecule from the ligand so as to obtain the purified ligand-binding molecule (see col. 33, lines 16-17, "[b]ound proteins are then removed from the solid support").

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Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Nock & Sydor (US 2002/0049152).

Nock & Sydor describe a method for purifying a ligand-binding molecule from a mixture, comprising:

(a) forming a carrier-ligand conjugate by reacting a C-terminal thioester on a carrier/ligand, with a nucleophilic group on a ligand/carrier, wherein cleaving a carrier-intein fusion protein or a ligand-intein fusion protein generates the C-terminal thioester (see para. [0055] *et seq.*; Fig. 1B);

(b) binding the carrier-ligand conjugate to a matrix (see para. [0049], second sentence, "subsequently immobilized to a surface"), and contacting the carrier-ligand conjugate with a mixture containing the ligand-binding molecule to selectively bind the ligand-binding molecule to the carrier-ligand conjugate (see para. [0135]); and

(c) eluting the ligand-binding molecule from the ligand so as to obtain the purified ligand-binding molecule (see para. [0136]).

Response to Arguments

In prior Office Action, claims 1-8 and 32 were rejected under 35 U.S.C. 102(e) as being anticipated by Muir *et al.* (US 6,875,594).

In response, Applicants argue that Muir *et al.* do not describe:

1. a carrier-ligand conjugate formed before attachment to the matrix;
2. how the ligand-binding molecule might be eluted from the protein array.

Applicants' arguments have been carefully considered but are not persuasive.

With respect to 1, Muir *et al.* appear to describe a method for forming a carrier-ligand conjugate (see Fig. 2A, product of step 3). Immediately following this step, Muir *et al.* appear to describe a step of binding the carrier-ligand conjugate to a matrix (see *e.g.*, col. 10, lines 46-47, "ligating by the method provided herein"; col. 19, lines 64+, "[t]he 'protein' component of a protein chip as used herein is the ligation product of an oligopeptide and a recombinantly expressed protein..."; Fig. 2A, step 4).

With respect to 2, Applicants' argument is not commensurate with the scope of Applicants' invention, as *claimed*. Claim 1 merely requires a step of "eluting the ligand-binding molecule from the ligand". Claim 1 does not require specific elution conditions. Thus, the step wherein "[b]ound proteins are then removed from the solid support" as recited col. 33, lines 16-17 of Muir *et al.* appears to sufficiently anticipate Applicants' invention, as *claimed*.

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Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE 08/28/06
SUPERVISORY PATENT EXAMINER
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